CLIA Updates

August 2022

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Inside This Issue

CLIA Regulation Changes!

CMS and CDC issued a final rule to update proficiency testing (PT) regulations related to analytes, acceptable performance for laboratories, PT referral, and administrative processes for PT programs established under CLIA. You can download the final rule from the Federal Register: Search for "CMS-3355-F."

1. The **effective date** of the revisions to PT requirements (§§ 493.2 and 493.801 through 493.959) will be **July 11, 2024**, two years after the publication date of this final rule in the Federal Register. The delayed effective date reflects the timeframe PT programs will need to produce or acquire PT samples to meet the revised regulations and incorporate any updates to PT reporting requirements. Review: QSO-22-21-CLIA (cms.gov) for more information to changes to the following PT specialties:
    a. Microbiology
    b. Non-Microbiology Analytes
        i. 29 New Analytes Finalized in subpart I
        ii. Five analytes deleted from subpart I
        iii. Criteria for Acceptable Performance
            1. § 493.927 General immunology
            2. § 493.931 Routine chemistry
            3. § 493.933 Endocrinology
            4. § 493.937 Toxicology
            5. § 493.941 Hematology
            6. § 493.959 Immunohematology
    c. Definitions
    d. Other Finalized Changes
2. **Effective date** for the regulations related to laboratories performing tests of moderate complexity and high complexity testing that also **perform waived testing** and proficiency testing enrollment (§§ 493.20 and 493.25) will be **August 10, 2022**.
        a. Testing of PT Samples, **PT Referral for Waived Tests**

CLIA Proposed Regulation Changes

CMS and CDC issued a proposed rule to update CLIA fee, histocompatibility and personnel, and alternative sanctions for Certificate of Waiver laboratories. You can download the proposed rule from the Federal Register:Search for "CMS-3326-P." For additional information please see the Fact Sheet [lnks.gd].

FREQUENTLY ASKED QUESTIONS

QUESTION. Where do I send/upload a copy of my CLIA certificate to update Medicaid? Medicaid is denying my bills, who do I contact?

ANSWER: Your CLIA Program does not deal with billing! Please refer to links listed below for the Claim Jumper articles, section Provider Services Portal News for directions and contacts.

- June 2022 Claim Jumper Newsletter (mt.gov) **has an article on uploading documents.**
- July 2022 Claim Jumper Newsletter (mt.gov) **has an article on moving away from faxes and mail.**

QUESTION. What are the minimum requirements for a Technical Supervisor?

ANSWER: SOM- Appendix C (cms.gov) CLIA Interpretive Guidelines

§493.1449

(c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; **and**

(c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology

The term "laboratory training or experience" means that the individual qualifying has the *training in and the experience with the specialties and subspecialties in which the individual is performing technical supervision.*

QUESTION. Where do individuals need to be licensed to work – primary and/or remote location?

ANSWER: (From CMS Baltimore) Individuals must be licensed to work in the state where the primary laboratory is located and the state where the remote laboratory is located.

Please note: All laboratories performing nonwaived testing must file a separate application for each laboratory location unless they are approved for one of the exceptions listed under §493.35, §493.43, and §493.55.

The individual must be licensed to work in the state where the primary laboratory is located because the remote laboratory is an extension of the primary laboratory and operates under the primary laboratory's CLIA certificate. In extending its enforcement discretion to remote/temporary sites, CMS required (1) that the designated primary site have a CLIA certificate using the address of the primary site (§493.35(b)(1), 43(b)(1), 55(b)(1)) and (2) the work being performed in the remote/temporary testing site falls within the parameters of the primary site's certificate. The CLIA certificate is granted to the laboratory at the primary site address; therefore, the parameters include compliance with that state's laws. As an extension of the primary lab, personnel must meet the state requirements where the primary lab is located regardless of the remote/temporary site's location.

CMS states in QSO-20-21-CLIA (cms.gov) that it is "exercising enforcement discretion to ensure pathologists may review pathology slides remotely." Specifically, CLIA currently allows pathology slides to be reviewed in locations that do not meet the requirements 42 C.F.R. 493.1274(a) (requiring slides to be reviewed at the site of the certified lab). CLIA did not say it is exercising enforcement discretion with respect to lab personnel qualifications

42 CFR 493.1274(c)(1)(i) provides that the slides must be reviewed by an individual who meets one of three qualifications. All three types of qualifications require that the individual (1) be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or (2) possess a current license as a cytotechnologist issued by the State in which the laboratory is located if such licensing is required. As a result, the physician/cytotechnologist needs to be licensed in the state where the primary site is located. If the remote testing site is in a different state, the physician/cytotechnologist must also be licensed in the state where the remote site is located.

TEST RECALL AND UPDATES

1. Extended Expiration Dates: Lucira Health and Ora Sure Technologies COVID-19Tests. At-Home OTC COVID-19 Diagnostic Tests | FDA
2. Haimen Shengbang Laboratory Equipment Co. Ltd. Recalls Viral Transport Media Containers That Are Not Authorized, Cleared, or Approved by the FDA | FDA
3. North American Diagnostics Recalls Oral Rapid SARS-CoV-2 Rapid Antigen Test Kits That Are Not Authorized, Cleared, or Approved by the FDA | FDA
4. American Contract Systems Recalls COVID Test Kits Nonsterile and Clean Catch Urine Kits for Risk of False Results | FDA

Please refer to the following link for additional recalls: Medical Device Recalls | FDA

Questions about the information discussed in this CLIA Update?
The Montana CLIA Program would love to answer them.
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If you would like to be added to the emailing list for future correspondence from the Montana CLIA program, please send an email to Michelle Griffin at Michelle.Griffin@mt.gov

References:
CLIA (mt.gov)
Clinical Laboratory Improvement Amendments (CLIA) | CMS
eCFR :: 42 CFR Part 493 -- Laboratory Requirements
QSO-20-21-CLIA (cms.gov)
QSO-22-21-CLIA (cms.gov)